

SMITHS MEDICAL MD, INC.
510(k) Premarket Notification

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K060036

PORT-A-CATH[®], PORT-A-CATH[®] II, ProPort[®], and P.A.S. PORT[®]
Implantable Venous Access Systems with Dual Layer Catheter
Summary of Safety and Effectiveness

MAY 17 2006

GENERAL INFORMATION

Applicant's Name and Address:	Smiths Medical MD, Inc. 1265 Grey Fox Road St. Paul, MN 55112
Contact Person:	Melanie Hess RN, BSN Regulatory and Clinical Affairs Associate
Common/Usual Name:	Implantable Access System
Proprietary Name:	PORT-A-CATH [®] , PORT-A-CATH [®] II, ProPort [®] , and P.A.S. PORT [®] Implantable Venous Access Systems with Dual Layer Catheter
Equivalence Device Comparison:	PORT-A-CATH [®] , PORT-A-CATH [®] II, ProPort [®] , and P.A.S. PORT [®] Implantable Venous Access Systems

II. DEVICE DESCRIPTION

PORT-A-CATH[®] Implantable Venous Access Systems with Dual Layer Catheter

The PORT-A-CATH[®] Implantable Venous Access Systems with Dual Layer Catheter are totally implantable access systems and are designed to permit repeated access to the venous system for the parenteral delivery of medications, fluids nutritional solutions and for the sampling of venous blood. The PORT-A-CATH[®] venous systems can be placed in the chest.

The PORT-A-CATH[®] Implantable Venous Access Systems with Dual Layer Catheter are totally implantable access systems consisting of the following components: a portal, catheter and connector. The components are assembled during implantation. The portals are available in titanium standard or Low Profile™, and the ULTRA-LOCK[®] catheter connector is utilized in the PORT-A-CATH[®] systems. The catheter is a Polyether block amide outer lining and an aliphatic polyurethane inner lining. This catheter will replace the current single layer polyurethane catheters on the equivalent Smiths Medical MD, Inc. PORT-A-CATH[®] Implantable Venous Access Systems. The systems are offered in either a kit or a tray configuration.

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PORT-A-CATH® II Implantable Venous Access Systems with Dual Layer Catheter

The **PORT-A-CATH® II** Implantable Venous Access Systems with Dual Layer Catheter are totally implantable access systems and are designed to permit repeated access to the venous system for the parenteral delivery of medications, fluids nutritional solutions and for the sampling of venous blood. The **PORT-A-CATH® II** venous systems can be placed in the chest.

The **PORT-A-CATH® II** Implantable Venous Access Systems with Dual Layer Catheter are totally implantable access systems consisting of the following components: a portal, catheter and connector. The components are assembled during implantation. The portals are available in polysulfone/titanium standard or Low Profile™, and the **ULTRA-LOCK®** catheter connector is utilized in the **PORT-A-CATH® II** systems. The catheter is a Polyether block amide outer lining and an aliphatic polyurethane inner lining. This catheter will replace the current single layer polyurethane catheters on the equivalent Smiths Medical MD, Inc. **PORT-A-CATH® II** Implantable Venous Access Systems. The systems are offered in either a kit or a tray configuration.

ProPort® Implantable Venous Access Systems with Dual Layer Catheter

The **ProPort®** Implantable Venous Access Systems with Dual Layer Catheter are totally implantable access systems and are designed to permit repeated access to the venous system for the parenteral delivery of medications, fluids nutritional solutions and for the sampling of venous blood. The **ProPort®** venous systems can be placed in the chest.

The **ProPort®** Implantable Venous Access Systems with Dual Layer Catheter are totally implantable access systems consisting of the following components: a portal, catheter and connector. The components are during implantation. The portals are available in plastic standard or Low Profile™, and the **SlideLock®** connector is utilized in the **ProPort®** systems. The catheter is a Polyether block amide outer lining and an aliphatic polyurethane inner lining. This catheter will replace the current single layer polyurethane catheters on the equivalent Smiths Medical MD, Inc. **ProPort®** Implantable Venous Access Systems. The systems are offered in either a kit or a tray configuration.

P.A.S. PORT® Implantable Venous Access Systems with Dual Layer Catheter

The **P.A.S. PORT®** Implantable Venous Access Systems with Dual Layer Catheter are totally implantable access systems and are designed to permit repeated access to the venous system for the parenteral delivery of medications, fluids nutritional solutions and for the sampling of venous blood. The **P.A.S. PORT®** venous systems can be placed in the arm or chest.

The **P.A.S. PORT®** Implantable Venous Access Systems with Dual Layer Catheter are totally implantable access systems consisting of the following components: a portal, catheter and connector. The components are assembled during implantation. The portals

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PORT-A-CATH®, **PORT-A-CATH® II**, **ProPort®**, and **P.A.S. PORT®**
Implantable Venous Access Systems with Dual Layer Catheter

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are available in titanium or plastic/titanium standard or Low Profile™, and the **ULTRA-LOCK®** catheter connector is utilized in the **P.A.S. PORT®** systems. The catheter is a Polyether block amide outer lining and an aliphatic polyurethane inner lining. This catheter will replace the current single layer polyurethane catheters on the equivalent Smiths Medical MD, Inc. **P.A.S. PORT®** Implantable Venous Access Systems. The systems are offered in either a kit or a tray configuration.

III. INTENDED USE OF THE DEVICE

PORT-A-CATH® Implantable Venous Access Systems with Dual Layer Catheter

PORT-A-CATH® Systems with Dual Layer Catheter are indicated when patient therapy requires repeated vascular access for injection or infusion therapy and/or venous blood sampling.

PORT-A-CATH® II Implantable Venous Access Systems with Dual Layer Catheter

PORT-A-CATH® II Systems with Dual Layer Catheter are indicated when patient therapy requires repeated vascular access for injection or infusion therapy and/or venous blood sampling.

ProPort® Implantable Venous Access Systems with Dual Layer Catheter

ProPort® Systems with Dual Layer Catheter are indicated when patient therapy requires repeated venous access for injection or infusion therapy and/or venous blood sampling.

P.A.S. PORT® Implantable Venous Access Systems with Dual Layer Catheter

P.A.S. PORT® Systems with Dual Layer Catheter are indicated when patient therapy requires repeated venous access for injection or infusion therapy and/or venous blood sampling.

IV. DEVICE COMPARISON

PORT-A-CATH® Implantable Venous Access Systems with Dual Layer Catheter

The **PORT-A-CATH®** Implantable Venous Access Systems with Dual Layer Catheter was compared to and found to be substantially equivalent to the following commercially available predicate systems with respect to indications for use and performance features: **PORT-A-CATH®** Implantable Venous Access Systems.

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PORT-A-CATH®, **PORT-A-CATH® II**, **ProPort®**, and **P.A.S. PORT®**
Implantable Venous Access Systems with Dual Layer Catheter

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PORT-A-CATH® II Implantable Venous Access Systems with Dual Layer Catheter

The **PORT-A-CATH® II** Implantable Venous Access Systems with Dual Layer Catheter was compared to and found to be substantially equivalent to the following commercially available predicate systems with respect to indications for use and performance features: **PORT-A-CATH® II** Implantable Venous Access Systems.

ProPort® Implantable Venous Access Systems with Dual Layer Catheter

The **ProPort®** Implantable Venous Access Systems with Dual Layer Catheter was compared to and found to be substantially equivalent to the following commercially available predicate systems with respect to indications for use and performance features: **ProPort®** Implantable Venous Access Systems.

P.A.S. PORT® Implantable Venous Access Systems with Dual Layer Catheter

The **P.A.S. PORT®** Implantable Venous Access Systems with Dual Layer Catheter was compared to and found to be substantially equivalent to the following commercially available predicate systems with respect to indications for use and performance features: **P.A.S. PORT®** Implantable Venous Access Systems.

V. SUMMARY OF STUDIES

A. Functional Testing

In-vitro testing was conducted in accordance with the FDA guidance, "Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters," dated March 16, 1995. All testing met product specification.

In-vivo testing of the new catheter material of the **PORT-A-CATH®**, **PORT-A-CATH® II**, **ProPort®**, and **P.A.S. PORT®** Implantable Venous Access Systems with Dual Layer Catheter was conducted to evaluate product performance. All testing met product specification.

Biocompatibility testing was conducted on system components. All testing passed.

Packaging and Sterilization systems are unchanged from predicate devices.

B. Clinical Studies

Human clinical studies were deemed not necessary to evaluate the safety or effectiveness of the **PORT-A-CATH®**, **PORT-A-CATH® II**, **ProPort®**, and **P.A.S. PORT®** Implantable Venous Access Systems with Dual Layer Catheter.

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C. Conclusions Drawn from the Studies

Based upon the information provided, the **PORT-A-CATH®**, **PORT-A-CATH® II**, **ProPort®**, and **P.A.S. PORT®** Implantable Venous Access Systems with Dual Layer Catheter is safe, effective and performs to established specifications.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2006

Ms. Melanie Hess
Regulatory and Clinical Affairs Associate
Smiths Medical MD, Incorporated
1265 Grey Fox Road
St. Paul, Minnesota 55112

Re: K060036

Trade/Device Name: PORT-A-CATH® Systems with Dual Layer Catheter,
PORT-A-CATH® II Systems with Dual Layer Catheter, ProPort® Systems
with Dual Layer Catheter, P.A.S. Port® Systems with Dual Layer Catheter

Regulation Number: 21 CFR 880.5965

Regulation Name: Subcutaneous, Implanted Intravascular Infusion Port and Catheter

Regulatory Class: II

Product Code: LJT

Dated: January 3, 2006

Received: January 5, 2006

Dear Ms. Hess:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

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PORT-A-CATH[®], PORT-A-CATH[®] II, ProPort[®], and P.A.S. PORT[®]
Implantable Venous Access Systems with Dual Layer Catheter
Indications for Use

510(k) Number (if known): TBD

Device Name: PORT-A-CATH[®] Systems with Dual Layer Catheter

Indications for Use:

"PORT-A-CATH[®] Systems with Dual Layer Catheter are indicated when patient therapy requires repeated vascular access for injection or infusion therapy and/or venous blood sampling."

Prescription Use X
21 CFR 801.109)

OR

Over-The Counter Use Per

Device Name: PORT-A-CATH[®] II Systems with Dual Layer Catheter

Indications for Use:

"PORT-A-CATH[®] II Systems with Dual Layer Catheter are indicated when patient therapy requires repeated vascular access for injection or infusion therapy and/or venous blood sampling."

Prescription Use X
21 CFR 801.109)

OR

Over-The Counter Use Per

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anthony D. Nwata

(Signature)
Division of Anesthesiology, General Hospital,
Injection Control, Dental Devices

510(k) Number: 15464436

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Implantable Venous Access Systems with Dual Layer Catheter
Indications for Use

510(k) Number (if known): TBD

Device Name: ProPort[®] Systems with Dual Layer Catheter

Indications for Use:

"ProPort[®] Systems with Dual Layer Catheter are indicated when patient therapy requires repeated venous access for injection or infusion therapy and/or venous blood sampling."

Prescription Use X
21 CFR 801.109)

OR

Over-The Counter Use Per

Device Name: P.A.S. Port[®] Systems with Dual Layer Catheter

Indications for Use:

"P.A.S. PORT[®] Systems with Dual Layer Catheter are indicated when patient therapy requires repeated venous access for injection or infusion therapy and/or venous blood sampling."

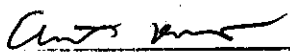
Prescription Use X
21 CFR 801.109)

OR

Over-The Counter Use Per

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Concurrence of CDRH, Office of Device Evaluation (ODE)


(On Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

(3) Number: 5 06 4032